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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/308,223	08/12/1999	GEORG KALLMEYER	P8341-9011	5876

7590

06/04/2002

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EXAMINER

NICKOL, GARY B

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 06/04/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/308,223

Applicant(s)

KALLMEYER ET AL.

Examiner

Gary B. Nickol Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13 and 15-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13 and 15-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Response to Amendment

The Amendment filed March 18, 2002 (Paper No. 18) in response to the Office Action of December 18, 2001 is acknowledged and has been entered. Claims 13, 15-36 are pending and are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Remarks:

The typographical error which applicant has indicated is noted (Paper No. 18, page 2). For the record, claims 13, and 15-36 stand rejected. There is no claim 115.

Rejections Maintained:

Claims 13, 15-21, and 23-36 remain rejected under 35 U.S.C. 102(e) as being anticipated by Andya *et al.* (US Patent No. 6,267,958, March 1996) for the reasons of record in Paper No. 17, pages 9-11.

Applicant's argue (Paper No. 18, page 4) that the reference specifically includes polyethylene glycol as a lycoprotectant in its formulation. Thus, applicant's argue, the reference

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constitutes a teaching away from the instant claimed lyophilizate which specifically excludes the presence of polyethylene glycol. This argument has been considered but is not found persuasive. The claims are not drawn to the exclusion of polyethylene glycol. On the contrary, they are drawn to a lyophilizate “essentially free of polyethylene glycols and additional proteins” wherein such a combination of polyethylene glycols and additional proteins is not specifically included nor necessitated in the teachings of Andya *et al.* Also, although the reference discloses several examples of lyoprotectants, including polyethylene glycol, such a disclosure does not constitute a teaching away from the claimed invention because disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). See MPEP 2123. Furthermore, a lyophilizate that is “essentially free” of polyethylene glycols is broader in scope as compared to a “lyophilizate which specifically *excludes* the presence of polyethylene glycols” as the former would be interpreted by one of ordinary skill as a lyophilizate which may comprise some residual amount of polyethylene glycols, in non-essential quantities.

Thus, applicants arguments have not been found persuasive, and the rejection is maintained.

Claims 13, and 15-36 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Andya *et al.* (US Patent No. 6,267,958, March 1996) in view of Michaelis *et al.* (US Patent No. 5,919,443, June 1995) for the reasons of record in Paper No. 17, pages 5-6.

Applicant's argue (Paper No. 18, page 4) that the reference of Michaelis *et al.* teaches the disadvantages of including high-molecular weight polymers in its preparation. This,

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applicants argue, is in distinct contrast to Adya *et al.*, whose preparation necessarily contains polymeric auxiliary substances. Applicants argue that where Andya teaches away from Michaelis, one skilled in the art would not have found any motivation to combine the references. This argument has been considered but is not found persuasive. Even if the reference of Michaelis *et al.* teaches the disadvantages of high-molecular weight polymers, there is no specific teaching in Adya *et al.* which necessitates the inclusion of polymeric auxiliary substances. Furthermore, the suggestion to combine was based on the advantages of an improved lyophilizate since Michaelis *et al.* make the surprising discovery that is possible to produce stable forms of pharmaceutical agents when amino sugars are used as additives (see Paper No. 17, page 6). Also, it appears that applicant has argued and discussed the references individually without clearly addressing the combined teachings, particularly in view of the fact that both references represent analogous teachings comprising the preparation of stable pharmaceutical compositions. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which made up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the cited references taken in combination. In re Young, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); In re Keller 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Furthermore, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference and it is not that the claimed invention must be expressly suggested in any one or all of the references; but rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art.

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In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Thus, applicants arguments have not been found persuasive, and the rejection is maintained.

All other rejections are withdrawn in view of applicants arguments there to.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
May 29, 2002

ALL
SUPERVISORY PATENT EXAMINER
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